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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,344	05/23/2005	Jan De Kroon	4662-254	6496
	7590 09/10/200 NDERHYE, PC	EXAMINER		
901 NORTH GLEBE ROAD, 11TH FLOOR			HAIDER, SAIRA BANO	
ARLINGTON, VA 22203			ART UNIT	PAPER NUMBER
			1711	
			MAIL DATE	DELIVERY MODE
			09/10/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)				
·	10/511,344	DE KROON ET AL.				
Office Action Summary	Examiner	Art Unit				
	Saira Haider	1711				
The MAILING DATE of this communication app Period for Reply	The MAILING DATE of this communication appears on the cover sheet with the correspondence address					
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS,						
WHICHEVER IS LONGER, FROM THE MAILING DA  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period v  - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tim will apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	N. nely filed the mailing date of this communication. D (35 U.S.C. § 133).				
Status						
1) Responsive to communication(s) filed on 31 M	1) Responsive to communication(s) filed on <u>31 May 2007</u> .					
2a)⊠ This action is <b>FINAL</b> . 2b)☐ This	This action is <b>FINAL</b> . 2b) This action is non-final.					
* *	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims						
4)⊠ Claim(s) <u>1,5 and 8-25</u> is/are pending in the application.						
4a) Of the above claim(s) is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.						
6)⊠ Claim(s) <u>1,5 and 8-25</u> is/are rejected.						
·	7) Claim(s) is/are objected to.					
8) Claim(s) are subject to restriction and/or election requirement.						
Application Papers						
9) The specification is objected to by the Examine	r.					
10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority under 35 U.S.C. § 119						
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).						
a) ☐ All b) ☐ Some * c) ☐ None of:						
1. Certified copies of the priority documents have been received.						
<ul> <li>2. Certified copies of the priority documents have been received in Application No</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage</li> </ul>						
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).						
* See the attached detailed Office action for a list of the certified copies not received.						
•						
Attachmont/s)		•				
Attachment(s)  1) Notice of References Cited (PTO-892)	4) 🔲 Interview Summary	(PTO-413)				
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) Paper No(s)/Mail Date						
3) Information Disclosure Statement(s) (PTO/SB/08)  Paper No(s)/Mail Date  5) Notice of Informal Patent Application 6) Other:						

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## **DETAILED ACTION**

1. The rejections have been altered to reflect the amended claims.

# Claim Rejections - 35 USC § 103

- 2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
- 3. Claims 1, 5 and 8-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bayer in view of Johnston.
- 4. Bayer discloses branched polyamide molding materials that are applied to polyolefin layers to form multilayer films (Col. 2, Line 43 to Col. 3. Lines25; Col. 6, Lines 15-23). Blow molding is noted as a preferred production method for the multilayer films (Col. 5, Line 64 to Col. 6, Line 7).
- Bayer fails to specify polypropylene or LLDPE as the polyolefins. Hence attention is directed towards the Johnston reference (Column: Lines:: abstract; 2:32-58; 3:68-4:4, 4:21-35, Table 1). Johnston teaches laminate films comprising outer polyolefin layers and a polyamide core layer. The reference teaches that containers are to be formed from the films, and that sterilization temperature controls the selection of the heat sealing inner layer. LLDPE and polypropylene layer are both suggested for the inner layer. LLDPE is also chosen when the sterilized medical product is filled in the container. Polypropylene is one of two materials to be used for the outer layer, especially linear biaxially oriented polypropylene. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to bond the polyamides of Bayer to either or both of polypropylene and LLDPE to provide a sterilizable container usable at a desired sterilization temperature.
- 6. In reference to claims 12-15 and 22-25, Johnston discloses that the multilayer film has a total thickness of about 75 to about 200 microns. The inner layer comprising either LLDPE or

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polypropylene has a thickness of about 50 to about 120 microns. The core layer comprising polyamide has a thickness of about 15 to about 50 microns. Johnston discloses that the combined dimensions of the core, inner and outer layers provide an improved container, if the total thickness is less than 75 microns the impact strength will not be sufficient, and if the total thickness is in excess of 200 microns the container will lack flexibility. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to form the multilayer film, as taught by the combination of Bayer and Johnston, in the aforementioned dimensions in order to ensure sufficient impact strength and flexibility.

7. In reference to claim 17, Bayer and Johnston in combination fail to disclose that the flown film has a blow-up ratio of from 20 to 40 %. It would have been obvious to one of ordinary skill in the art at the time of the invention to control the blow-up ratio, wherein the blow-up ratio of the blown film is a readily manipulatable parameter. The motivation to modify the blow-up ratio is to control the diameter of the final product while blown in the die or mold cavity, instead of modifying the size of the die or cavity. It is noted that the final product of Johnston includes bags and container, in particular for conveying or storing liquids or gases (col. 2, lines 20-32).

## Response to Arguments

- 8. Applicants' arguments with respect to the rejection of the claims based on the Schmitz et al. reference have been considered but are moot in view of the new ground(s) of rejection.
- 9. Applicants have argued that the Bayer reference provides no motivation to utilize the branched polyamide in place of an unbranched polyamide. The examiner notes that the basis of the rejection is not the substitution of a branched polyamide for an unbranched polyamide. Rather, as unambiguously set forth in the rejection above, the basis of the obviousness rejection is that of

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utilizing polypropylene and/or LDPE as the polyolefin in the disclosed multilayer structure of Bayer.

- 10. In support of their argument for lack of motivation, applicants have cited a portion of the Bayer reference which states that the inventive polyamide of Bayer can be processed via known processes known in the prior art for polyamides (col. 5, lines 64+). Applicants have alleged that this statement in Bayer explicitly reports to the art that branched polyamides are equivalent to other branched polyamides, including unbranched polyamides. Assuming arguendo that applicants' statement is true, it would have been obvious to one of ordinary skill in the art at the time of the invention to utilize either unbranched or branched polyamides given the teachings alleged by applicant, that Bayer recognizes the branched and unbranched polyamides as equivalent. However, this is not the instance herein, and Bayer does not recognize unbranched or branched polyamides as equivalent. Thus, rendering applicants' arguments invalid.
- 11. Applicants have argued the presence of unexpected results due to the use of a branched polyamide layer in a multilayer structure. The examiner has considered the allegation of unexpected results and concludes that the statements and examples provided in the specification are insufficient to establish unexpected results. Specifically, attention is directed to comparative experiment A and example 1, wherein the comparative experiment contains a non-branched polyamide and the example contains a branched polyamide. The difference in the Elmendorf tear strength of the two is 2 kN/m, this difference cannot unequivocally be attributed to the presence or lack thereof of branched polyamides. Rather the difference may readily be attributed to standard error measurements or an expected difference due to the presence or lack thereof of branched polyamides. Further, applicants have stated that the bubble stability of example 1 was markedly better that in the comparative experiment. There is no explanation of the evidence gathered resulting

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in the conclusion of "markedly better," rather this statement is not found to be of substantial evidentiary value and thus does not support applicants' argument of unexpected results.

12. In order to establish unexpected results applicant is directed to MPEP § 716, which clearly sets forth the requirements for the establishment of unexpected results.

#### Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Saira Haider whose telephone number is (571) 272-3553. The examiner can normally be reached on Monday-Friday from 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck can be reached on (571) 272-1078. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <a href="http://pair-direct.uspto.gov">http://pair-direct.uspto.gov</a>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Saira Haider Examiner Art Unit 1711

James J. Seidleck
Supervisory Patent Examiner
Technology Center 1700